

Centers for Disease Control and Prevention

July 30, 2009

Dear Provider:

I am writing to stress the critical importance of reinstating the booster dose of Hib vaccine for children 12 through 15 months of age. CDC has heard that some providers are choosing to delay reinstating the Hib booster dose until increased supplies of a monovalent Hib vaccine product are available. This is a practice that should not be implemented. The full series, including the booster dose, is absolutely essential to fully protect infants.

Beginning in July 2009, sanofi pasteur, the manufacturer of the two available Hib-containing vaccines in the U.S., has been able to increase the number of doses of these Hib-containing vaccines. As a result, CDC recommends reinstatement of the booster dose and limited catch-up with currently available products (monovalent and combination). Older children for whom the booster dose was deferred should receive their booster dose at their next routinely scheduled visit or medical encounter. Although supply is sufficient to reinstate the booster dose and begin catch-up vaccination, there is not enough supply to support immediate recall of all children with deferred booster doses.

The current challenge is that even though there is enough supply to return to the full Hib vaccine series, including the 3 dose primary series and the booster dose, there is an increasing supply of the combination vaccine DTaP-IPV/Hib (Pentacel) but a near stable supply of the monovalent Hib vaccine. To reinstate the booster dose and maximize the number of children protected from Hib, most practices will need to incorporate DTaP-IPV/Hib, even if this is not their preference. Because of the amounts and types of Hib-containing vaccine that are currently available, full choice of Hib vaccine product is not an option for the VFC program and providers at this time. In addition, current Hepatitis B supply constraints mean that providers must be especially vigilant in planning ahead for the type of Hib and Hepatitis B vaccine products available in their practice, to minimize extra immunizations and provide timely protection.

Immunization providers have had an incredible job of managing the Hib vaccine shortage during the past 18 months. In terms of disease incidence, the Hib experts at CDC have not seen any increase in invasive Hib disease due to the shortage. This is extremely fortunate news that we

hope will continue to be the case through the remainder of the catch-up period. However, given the extended duration of the shortage, and the potential for increased nasopharyngeal carriage of the Hib bacterium, it is critical that providers continue to provide children with the full primary series and return to including the booster at this time.

We believe that we are in the final stretch of the Hib vaccine shortage. GSK has announced that their application for licensure for another monovalent Hib vaccine (Hiberix; GSK) was submitted in March 2009. This product will only be licensed for the booster dose. In addition, Merck anticipates bringing their monovalent Hib vaccine back to the market in limited amounts by the end of this calendar year, with full supply beginning in first quarter of 2010. Despite these positive forecasts, we cannot predict with certainty when these additional monovalent products will become available.

The United Kingdom recently published a review of their experience that showed the importance of the booster dose in reducing carriage. Reduction of carriage provides direct and indirect protection from invasive Hib disease. Since the start of their program, the UK has vaccinated with only a primary series. The booster dose is needed to reduce carriage of the bacterium; and the accumulation of toddlers without this protection from carriage means that Hib has or will soon creep back into the population and be able to infect an incompletely protected infant – one that is too young or did not receive the full primary series.

Unlike the U.S., they had ongoing transmission of Hib that prompted them to institute a booster dose, after which their rates of invasive Hib disease declined. Since we now have enough vaccine to reinstate the booster dose for routine use, we must use the available vaccine products to do this as soon as possible in order to protect our children.

We know that it is a shared goal among all providers who care for children and all public health practitioners to continue to keep invasive Hib disease at bay and we have been very fortunate throughout the current shortage. As we near the end of Hib vaccine supply constraints, we must administer the products available to ensure that the Hib booster dose is being reinstated and children are receiving the full vaccine series.

Thank you,

Anne Schuchat, M.D.

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Director, National Center for Immunization and Respiratory Diseases

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